

42. (New) The vector according to claim 40, wherein the sequence encoding the fragment of the protein(s) of (b) is present in antisense orientation.

REMARKS

Reconsideration and withdrawal of the claim rejections are requested in view of the amendments and remarks herein.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-5, 7--21, 24, and 26-42 are under consideration in this application. Claims 1-5, 7-21 and 24 have been amended; claims 6 and 25 have been cancelled; claims 26-42 have been added to round out the scope of protection to which Applicants are entitled.

Support for the amended claims is found throughout the specification. Specifically, support for the recitation "under stringent conditions" in claims 1 and 2 can be found on page 13, lines 34-38 of the application. Support for the recitation of "85% sequence identity" can be found on page 14, lines 19-21. Support for the amendments to claim 10 can be found on page 17, lines 9-13. Support for new claims 27-42 can be found in claims 8 and 9, as originally filed, on page 13, lines 28-32, on page 20, lines 22-36, and in the paragraph bridging pages 21 and 22.

No new matter is added.

The objections to claim 6 has been obviated by the cancellation of claim 6.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

Formal Drawings

In response to the Notice of Draftsperson's Patent Drawing Review, a new copy of Figure 1 is provided. It should be noted that the line in the graph of Figure 1 is not smooth because a jagged line is required to accurately represent the data. Reconsideration and withdrawal of the objections to the drawing are requested.

II. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH ARE OVERCOME

The Application Contains Adequate Written Description

Claims 1-21 and 24-25 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The rejection is traversed.

Claim 1 has been amended to encompass (a) the nucleic acid molecule encoding the protein of SEQ ID NO:2; (b) the nucleic acid molecule of SEQ ID NO:1, or nucleic acid molecules with at least about 85% sequence identity thereto; (c) nucleic acid molecules that hybridize under stringent conditions with or are complementary to (a) or (b); and (d) nucleic acid molecules whose sequences deviate from those of (a)-(c) due to the degeneracy of the genetic code.

As admitted on page 3 of the Office Action, there is clearly written description for the DNA sequence of SEQ ID NO:1 encoding the amino acid sequence of SEQ ID NO:2. The inclusion in claim 1 of a nucleic acid molecule having at least about 85% sequence identity to SEQ ID NO:1 is also adequately described. Therefore, limitations regarding both the structure and function of the claimed nucleic acid molecules are present in claim 1.

The phrase “under stringent conditions” has been added to part (c) of claim 1 and to part (b) of claim 2 to more clearly define how hybridization is to be performed. The section of the specification beginning on page 13, line 34 discusses hybridization and discloses the preferred conditions.

The claimed nucleic acid molecule of claim 1 and the polypeptide it encodes are described functionally and structurally by sequence identifiers and hybridization conditions. Hybridization techniques using a known nucleotide sequence (*e.g.* SEQ ID NO: 1) as a probe under stringent conditions were conventional in the art at the time of filing. A person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the stringent hybridization conditions set forth in the claim yield structurally similar polynucleotides. Therefore, a representative number of species is disclosed, and claim 1, drawn to a genus of nucleic acids that hybridize with a given sequence and encode a protein with a specified activity, is adequately described. (See Example 9 of the USPTO’s “Synopsis of Application of Written Description Guidelines”).

The Claims Are Enabled

Claims 1-21 and 24-25 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

As discussed above, claim 1 has been amended for clarity and to remove reference to derivatives or parts of SEQ ID NO:1. As claim 1 currently reads, there would be no undue experimentation on the part of the skilled artisan to isolate a nucleic acid molecule that encodes the amino acid sequence of SEQ ID NO:2, or that has the nucleotide sequence of SEQ ID NO:1, or that has at least about 85% sequence identity to SEQ ID NO:1. Further, specific guidance is given in the specification regarding how to isolate a nucleic acid molecule that hybridizes under stringent conditions to either of the aforementioned nucleic acid molecules. As discussed above, claim 1 unambiguously recites the structure of the claimed molecules. In addition, claim 1 contains the functional limitation that the nucleic acid molecule has the function of a potato β -amylase. The specification provides clear direction for determining the starch content of a transgenic plant or plant cell to determine whether β -amylase activity has been modified (see, for example, the section of the specification beginning on page 39, line 29). Further, procedures for identifying, by structural characteristics, a nucleic acid molecule having at least about 85% identity to SEQ ID NO:1 are standard in the art. There is no reason to expect that one of skill in the art could not identify a member of the claimed genus based on its structural and functional characteristics.

Added claims 27-42 relate to the use of fragments of the nucleic acid encoding SEQ ID NO:2 in antisense or cosuppression embodiments of the invention. These aspects were included and intended in the original claims, e.g. in the recitation of “derivatives or parts” in claim 1 and “antisense orientation” in claims 8 and 9. In the last paragraph on page 5, the Office Action points out instances in which an antisense approach was unsuccessful. The Examiner is respectfully reminded that the standard for enablement precludes undue experimentation, not any experimentation at all. It is well within the skill of one in the art to construct oligonucleotides for antisense or cosuppression and to test said oligonucleotides for their ability to alter starch content and/or quality in a transgenic plant or plant cell.

It is submitted that the claims are in compliance with the first paragraph of §112, and reconsideration and withdrawal of the rejections thereunder are requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, 2ND PARAGRAPH ARE OVERCOME

Claims 1-21 and 24-25 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

Claim 1 was rejected for reciting “preferably which hybridize specifically”, which recitation has been deleted from claim 1.

Claim 6 was rejected for reciting “preferably specifically hybridizes”. Claim 6 has been cancelled, obviating the rejection.

Claim 10 was rejected for reciting “partly present in sense orientation and partly in antisense orientation”. Claim 10 has been amended, obviating the rejection.

Claim 21 was rejected for not reciting any method steps. Claim 21 has been amended to overcome this rejection.

Claim 24 was rejected for reciting “preferably bacterial or plant cells”. Claim 24 has been rewritten to remove the word “preferably”.

Claims 24 and 25 were rejected for providing a use without any method steps. Claim 25 has been cancelled.

Claim 8 was rejected for reciting “soluble starch synthase III”. This was an inadvertent error, which has been corrected by the substitution of “ β -amylase” for “soluble starch synthase III”.

It is believed that the claims meet the requirements of 35 U.S.C. §112, second paragraph, and reconsideration and withdrawal of the rejections are requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §101 ARE OVERCOME

Claims 24 and 25 were rejected under 35 U.S.C. §101 for allegedly providing a use without any method steps. Claim 25 has been cancelled.

Claims 1, 3, 5 and 6 were rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. Claim 1 has been amended to specify an “isolated” nucleic acid molecule, obviating this rejection.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §101 are requested.

V. THE REJECTION UNDER 35 U.S.C. §102 IS OVERCOME

Claims 1-12 and 24 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Yoshida *et al.* The rejection is traversed.

Yoshida *et al.* relates to sweet potato β -amylase, the sequence of which was published in Yoshida, 1992, Gene 120 or as EMBL Accession No. D12882. Initially, it is noted that Yoshida *et al.* does not relate to potato β -amylase, as is recited in the present claims, but to sweet potato β -amylase, which is an entirely different molecule.

As is shown in the attached sequence alignment, the sequence identity between the β -amylase of Yoshida *et al.* and that of the present invention is only 54.9%, which is clearly outside of the scope of the instant claims. (Introns were removed from the Yoshida sequence in order to ensure accurate alignment.)

Therefore, the subject matter of the present invention is clearly novel over Yoshida *et al.*, and reconsideration and withdrawal of the rejection under 35 U.S.C. §102 are requested.

VI. THE REJECTION UNDER 35 U.S.C. §103 IS OVERCOME

Claims 1-21 and 24-25 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Taylor *et al.* in view of Yoshida *et al.* The rejection is traversed.

As discussed above, the teachings of Yoshida *et al.* are distinct from those of the instant invention, as it does not teach or suggest a nucleic acid molecule with the sequence of SEQ ID NO:1, or a nucleic acid molecule with at least 85% sequence identity to SEQ ID NO:1, or a nucleic acid molecule which encodes a protein with the sequence of SEQ ID NO:2. In view of the low degree of sequence identity and the distribution of identical nucleotide positions between Applicants' sequence and Yoshida's sequence, the skilled artisan would not have been able to arrive at the instant invention with or without Taylor *et al.*

Further, Yoshida *et al.* state that β -amylases are "not essential in the metabolism of storage starch in [tuberous roots]." (See page 225, 2nd column, 2nd paragraph.) Instead, Yoshida *et al.* suggest, on page 258, 3rd paragraph, that β -amylase proteins are likely to be storage proteins. This clearly teaches away from the present invention, which is related to the modification of starch by regulating the enzymatic activity of β -amylases.

Therefore, neither Yoshida *et al.* nor Taylor *et al.*, alone or in combination, teach or suggest the instant invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103 are requested.

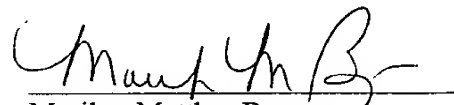
CONCLUSION

In view of the remarks and amendments herewith, it is believed that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By:



Marilyn Matthes Brogan
Registration No. 31,223
(212) 588-0800